

Remarks

Claims 5, 9 and 13 are herein amended to independent form as stated in the Office action on page 7, ¶8. Support for amendment to claim 5 is found in claims 1, 4 and 5 as originally filed. Support for amendment to claim 9 is found in claims 6, 7, 8 and 9 as originally filed. Support for amendment to claim 13 is found in claims 10, 11, 12 and 13 as originally filed.

Claim 14 is herein amended to correct a clerical error as stated in the Office action on page 2, ¶2.

No new matter has been added, and no new material presented that would necessitate an additional search on the part of the Examiner. Claims 1-15 are pending herein.

Claims are novel

The Office action on page 4 rejects claims 1-4 and 10-12 under 35 U.S.C. §102(b) in view of Declerck et al. (Automatic Registration and Alignment on a Template of Cardiac Stress and Rest Reoriented SPECT Images, *IEEE Transactions on Medical Imaging*, Vol. 16, No. 6, December 1997).

The legal standard for rejection of a claim under 35 U.S.C. §102 is identity. "To anticipate a claim, the reference must teach every element of the claim." MPEP §2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." MPEP §2131.02., *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants show below that Declerck is not the same as the subject matter

of the present claims, and therefore fails to anticipate the claims.

Declerck et al. (IEEE Transactions on Medical Imaging, Vol. 16, No. 6, December 1997)

Declerck shows comparing single photon emission computed tomography (SPECT) images, having a rest image and a stress image, to provide a classification of the myocardium. See Declerck, page 727. Declerck shows a 3-D matching procedure to match stress and rest images to a template image of the heart to compare stress and rest perfusion images of a patient. Ibid., page 728. The stress image and rest image are matched using a feature-points-based method, which yields an affine transformation defining a correspondence between a point in the stress image and a point in the rest image. Ibid., page 728.

A template heart in Declerck is matched to the stress image using local spline transformations, and the stress and rest images are resampled in its geometry. Ibid., page 728, column 2, line 28 - page 29, column 1, line 1. The output of this transformation is a new stress/rest pair in a new geometry, and the coordinates of a 3-D voxel in any of the stress, rest, or template images correspond to the same part of the myocardium, allowing comparison. Ibid., page 729, column 1, lines 5-9.

Declerck detects the edges of the heart in the image using a Canny-Deriche recursive filter algorithm in a 3-D polar geometry. Ibid., lines 21-24. After using the recursive algorithm to detect the edges of the heart, Declerck filters the edge points with a priori constraints to eliminate points from other organs. Ibid., column 2, lines 1- page 730, column 1, line 2. Declerck then uses the same a priori filtering constraints to determine the edges of the template image. Ibid., p. 730, column 2, lines 2-4.

Declerck then defines a transformation of the stress image which deforms the stress image edge points to the rest image edge points using an enhancement of the Iterative Closest Point algorithm. Declerck p. 730, column 2, lines 15-16. In this enhancement Declerck seeks a matching function f whereby given a point M in image 1, $f(M)$ should be the equivalent point in image 2. Ibid., lines 17-19. To make this calculation, Declerck defines a criterion C which is “the sum of all residual distances extended to S_1 , a subset of the feature points in Image 1 for which the matching is considered as being reliable.” Ibid., p. 730, column 2, line 22- p.731, column 1, line 4. Declerck then puts the C through a minimization process which starts with an initial transformation f_0 which is a uniform scaling of the images to the same size under the assumption that they are similarly aligned. Ibid., p. 731, column 1, lines 5-10. Declerck then performs a series of three step iterations on S_1 . Ibid., lines 10-11. The iterations stop when a maximum number of iterations is reached or when $S_{1,n}=S_{1,n-1}$ not when an optimal profusion parameter is found. Ibid., column 2, lines 4-5.

To match the stress to the rest image Declerck uses an affine transformation with a maximum of ten iterations for each transformation. Ibid p.732, column 2. lines 13-15. To match the template to the stress image, Declerck uses a local spline transformation with six iterations after the rigid and affine transformations. Ibid., lines 15-18. Declerck then resamples the stress image in the geometry of the template image and then resamples the resultant image in the geometry of the rest image. Ibid. p. 733, column 1, lines 10-13. “The resampling is a purely geometric transformation, the integral count density information is not preserved.” Ibid., lines 14-15 [emphasis added].

Then Declerck performs a polar transformation of the image which normalizes the image by reducing all morphological attributes to angular coordinates. Ibid. p.733, column 2, lines 23-25. Declerck performs this normalization by radial sampling using the center of the left ventricle as the center of the radius. Ibid., lines 8-10. Then Declerck reports the maximal intensity along the radii on the 2D polar image. Ibid., lines 10-11.

In contrast to the present claims as here amended, Declerck fails to show repeating the steps of defining at least one contour of an organ and establishing at least one perfusion parameter of a region of interest of the organ within a boundary defined by the at least one contour in a series of iterative steps where at least one contour is varied, as is the subject matter of claim 1. Declerck normalizes stress, rest, and template images, and applies recursive algorithms and a priori constraints to filter and geometrically define edge points. Then Declerck resamples the image and reduces the morphological attributes to polar 2-D angular coordinates before reporting the maximum intensities for all the polar radii of the image. One of ordinary skill in the art of medical imaging would have known at the time the present application was filed, that recursive algorithms are not the same as iterative algorithms. Further, one skilled in the art of medical imaging at the time the application was filed would have known that reducing morphological attributes to polar 2-D angular coordinates is not the same as varying a contour of an image to reach an optimal perfusion parameter.

Declerck also fails to show a series of iterative steps that is terminated after reaching an optimal value for the at least one perfusion parameter, as is the subject matter of claim 1. In contrast, Declerck uses iteration to geometrically define organ edges in images and to normalize images, not to reach an optimal value for a perfusion parameter. When using

iteration, Declerck terminates the iteration at a predetermined number of iterations or when $S_{1,n}=S_{1,n-1}$, not when an optimal perfusion parameter is reached.

For any of these reasons, Declerck is not the same as claim 1, therefore this claim is not anticipated by Declerck. Claims 2-4 and 10-12 depend directly or indirectly on claim 1 and incorporate all of the subject matter of this claim and contains additional subject matter. Therefore claims 2-4 and 10-12 also are not anticipated by Declerck.

Applicants respectfully request withdrawal of rejection of claims 1-4 and 10-12 under 35 U.S.C. §102(b).

Claims comply with 35 U.S.C. §103(a)

The Office Action on page 6 rejects claims 6-8 and 14-15 under 35 U.S.C. §103(a) in view of Declerck et al. (Automatic Registration and Alignment on a Template of Cardiac Stress and Rest Reoriented SPECT Images, *IEEE Transactions on Medical Imaging*, Vol. 16, No. 6, December 1997) in combination with Aiazian (U.S. patent number 7,024,024, issued April 4, 2006).

Declerck et al. (*IEEE Transactions on Medical Imaging*, Vol. 16, No. 6, December 1997)

Declerck is characterized above.

Declerck fails to teach or suggest a software program or an apparatus that executes a method for repeating the steps of defining at least one contour of an organ and establishing at least one perfusion parameter of a region of interest of the organ within a boundary defined by the at least one contour in a series of iterative steps where at least one contour is varied, as is the subject matter of claims 1 and 6.

In contrast to the present claims, Declerck normalizes stress, rest, and template images, and applies recursive algorithms and a priori constraints to filter and geometrically

define edge points. Then Declerck resamples the image and reduces the morphological attributes to polar 2-D angular coordinates before reporting the maximum intensities for all the polar radii of the image. One of ordinary skill in the art of medical imaging would have known at the time the present application was filed that recursive algorithms are not the same as iterative algorithms. One skilled in the art of medical imaging would further have known that reducing morphological attributes to polar 2-D angular coordinates is not the same as varying a contour of an image to reach an optimal perfusion parameter.

Declerck further fails to teach or suggest that the series of iterative steps is terminated after reaching an optimal value for the at least one perfusion parameter, as is the subject matter of claims 1 and 6. In contrast, Declerck uses iteration to geometrically define organ edges in images and to normalize images, not to reach an optimal value for a perfusion parameter. When using iteration, Declerck terminates the iteration at a predetermined number of iterations or when $S_{1,n}=S_{1,n-1}$, not when an optimal perfusion parameter is reached.

Most important, Declerck fails to teach or suggest a software program for a computer or an apparatus implemented to execute a method for analyzing perfusion images, as admitted in the Office Action on page 6, lines 18-19. For these reasons Declerck alone does not render obvious claims 1 and 6.

Claims 7-8 and 14-15 depend directly or indirectly on claims 1 and 6 respectively and incorporate all of the subject matter of these claims and contain additional subject matter. Therefore claims 7-8 and 14-15 also are not obvious in view of Declerck.

Applicants now characterize the additional reference cited in combination with Declerck prior to analyzing the combination.

Aiazian, U.S. patent number 7,024,024, issued April 4, 2006

Aiazian shows enhancing analysis of in vivo images by providing automatic calculation and display of normalized data sets and multi-dimensional images. See Aiazian, column 1, lines 65-67 to column 2, lines 1-2. Aiazian shows calculating a statistical median reflection energy intensity value and generating an electronic image of the chosen body region based on the median reflection energy intensity values. Ibid., column 10, lines 51-57. Aiazian shows further enhancing images by providing automated or semi-automated division of in vivo images into user-defined multi-dimensional segments. Ibid., column 2, lines 2-5. Comparison studies of regions are performed by simultaneously displaying corresponding regions of interest imaged at distinct periods of time. Ibid., column 2, lines 5-8. To normalize the data prior to display, Aiazian uses an internal reference point, an external reference point, an arbitrary value, a mean of all values, and a baseline. Ibid., column 5, lines 59-62. The elimination of baseline data from the final data set is accomplished by subtracting a desired baseline data set from the acquired perfusion data. Ibid., column 4, lines 57-60.

Nowhere does Aiazian teach or suggest any software program or apparatus that executes a method of repeating the steps of defining at least one contour of an organ and establishing at least one perfusion parameter of a region of interest of the organ within a boundary defined by the at least one contour in a series of iterative steps where at least one contour is varied, as is the subject matter of independent claims 1 and 6.

Further, nowhere does Aiazian teach or suggest any software program or apparatus that implements a method in which the series of iterative steps is terminated after reaching

an optimal value for the at least one perfusion parameter, as is the subject matter of claims 1 and 6.

For these reasons, Aiazian fails to cure the defects of Declerck with respect to claims 1 and 6. Therefore claims 1 and 6 are not obvious in view of Declerck and Aiazian, alone or in combination.

Claims 7-8 and 14-15 depend directly or indirectly from claim 1 or 6 and incorporate all of the subject matter of these claims and contain additional subject matter. Therefore, these claims also are not obvious in view Declerck and Aiazian, alone or in combination.

Legal analysis

Whether an invention complies with 35 U.S.C. §103(a) is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

The *Manual of Patent Examining Procedure* states: "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." [emphases added] *Manual of Patent Examining Procedure* §2142 (8th Ed. Rev.2, May 2, 2004); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

A recent decision by the U.S. Supreme Court, *KSR International Co. v. Teleflex Inc.* 550 U.S. ____ (2007), discusses criteria for showing a motivation to combine numerous prior

art references in a determination that a claimed invention is obvious. The U.S. Supreme Court in *KSR* explained that “[t]here is no necessary inconsistency between the idea underlying the TSM [teaching, success, motivation] test and the *Graham* analysis.” *KSR International Co.* 550 U.S. ____ at p. 15. In fact, the court explains “... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the newly claimed invention does.” *Ibid.*

Failure of the cited prior art to teach or suggest all the claim limitations

To establish a *prima facie* case for obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *Manual of Patent Examining Procedure*, §2143.03, p. 108 (8th Ed. Rev.2, May 2, 2004); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Claims 1 and 6 are directed in part to varying the definition of the image contour in each iteration and terminating the iterations when an optimal value for the perfusion parameter is reached. Applicants show below that the combination of Declerck and Aiazian does not teach or suggest this subject matter of claims 1 and 6.

Declerck uses iteration to geometrically define organ edges in images and to normalize images. When using iteration, Declerck terminates the iteration at a predetermined number of iterations or when $S_{1,n}=S_{1,n-1}$. Further, Declerck shows normalizing perfusion images to templates then reducing the images to numerical coordinates. Nowhere does Declerck teach or suggest terminating the iterations when obtaining an optimal perfusion parameter. Nowhere does Declerck teach or suggest varying the contour definition with each iteration. Therefore, Declerck does not teach the subject

matter of claims 1 and 6. Applicants show below that Aiazian does not cure the defects of Declerck.

Aiazian generates an electronic image of the chosen body by calculating a statistical median of reflected energy values. Aiazian further enhances and normalizes the image by subtracting a desired baseline data set from the perfusion data. Nowhere does Aiazian teach or suggest terminating iterations when obtaining an optimal perfusion parameter. Nowhere does Aiazian teach or suggest varying the contour definition with each iteration. Therefore, Aiazian does not cure the defects of Declerck.

As shown by the factual analysis above, the cited references fail to teach or suggest varying the definition of the image contour in each iteration and terminating the iterations when an optimal value for the perfusion parameter is reached, to which claims 1 and 6 are directed.

Therefore, by the legal criteria discussed above, the underlying facts of the content of the cited prior art and of the present pending claims show that the prior art fails to teach or suggest the claims of the present invention.

Therefore, a *prima facie* case that claims 1 and 6 of the present invention are obvious has not been made.

Claims 7-8 and 14-15 depend directly or indirectly from claims 1 and 6, respectively, and incorporate the subject matter of claims 1 and 6 and contain additional subject matter. Therefore these claims also are not obvious in light of the cited combination of references.

For at least these reasons, obviousness of the claims has not been established.

No motivation to combine references

To establish that a claim does not comply with 35 U.S.C. §103(a) based on a combination of the elements disclosed in the prior art in the absence of any hindsight, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicants. *Manual of Patent Examining Procedure*, §2143.01, p. 135 (8th Ed. Rev.3, August, 2005); *In re Fulton*, 391 F.3d at 1200-01, 73 USPQ2d at 1145-46 (Fed. Cir. 2004). The teaching or suggestion, not merely to make the claimed combination, but also of a reasonable expectation of success, must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488; 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The U.S. Supreme Court in *KSR International Co. v. Teleflex Inc.* affirmed the legal principle that the mere fact that each element of a claimed invention could be found within the prior art does not render the claimed invention obvious. The court stated:

.... A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co.* 550 U.S.____ at p. 14

“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” *Manual of Patent Examining Procedure*, (Eighth Edition, Rev. 3, August 2005), §2143.01, p. 138; *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Applicants show below that there is no motivation to combine Declerck and Aiazian to arrive at the subject matter of the present claims because such a combination would require a change in the principle of operation of Declerck.

Declerck shows using templates of normal hearts to analyze perfusion data by deforming and normalizing rest and stress perfusion images to the template. The stress and rest images of the heart being studied are deformed to match the contours of the normal heart template through a series of calculations using recursive and iterative algorithms, thus highlighting perfusion when the template heart is compared to the stress and rest images normalized to the template heart image. Factual analysis above demonstrates that Declerck's method requires these templates.

Aiazian shows using computer software to represent perfusion data on the screen in side by side comparisons. Aiazian shows further enhancing images by providing automated or semi-automated division of in vivo images into user-defined multi-dimensional segments.

Factual analysis demonstrates that Aiazian does not operate using templates. Instead of normalizing perfusion images to a template image, Aiazian subtracts a baseline data set from the perfusion data and generates the image from a calculated statistical mean of image intensities. To combine these two references would require abandoning Declerck's reliance on constructed templates for analyzing perfusion images, which are the central principle of operation in Declerck. Therefore, there is no motivation to combine these references as such a combination would require a change in the principle of operation of Declerck's method.

For any of the above reasons, Applicants respectfully request withdrawal of rejection of claims 6-8 and 14-15 under 35 U.S.C. §103(a).

Non-statutory double patenting issues

The Office Action on p. 3 rejects claims 1 and 10 under the judicially created doctrine of double patenting in view of U.S. patent number 7,047,061.

The Office Action on p. 3 states that "... a timely filed Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional

rejection based on a non-statutory double patenting ground ..." Accordingly, Applicants provide here a Terminal Disclaimer for co-owned issued patent having U.S. patent number 7,047,061.

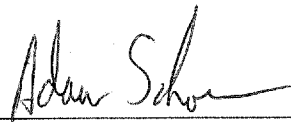
Upon entry of the Terminal Disclaimer attached hereto, rejection under the judicially created doctrine of double patenting can properly be withdrawn, an action which is respectfully requested.

Summary

On the basis of the foregoing reasons, Applicants respectfully submit that the pending claims are in condition for allowance, which is respectfully requested.

If there are any questions regarding these remarks, the Examiners are invited and encouraged to contact Applicants' representative at the telephone number provided.

Respectfully submitted,



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Date: June 26, 2007